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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

*Ex parte* CARLOS PICORNELL DARDER

Appeal 2009-001922  
Application 09/491,624  
Technology Center 1600

Oral Hearing Held: Wednesday, July 8, 2009

Before DEMETRA MILLS, ERIC GRIMES, and RICHARD M. LEOVITZ, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANT:

VINCENT M. FAZZARI, ESQ.  
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The above-entitled matter came on for hearing on Wednesday, July 8, 2009, commencing at 1:30 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Hearing Room A, Alexandria, Virginia, before Laurie B. Allen, Notary Public.

1 MR. FAZZARI: Good afternoon.

2 JUDGE MILLS: Just to let you know, we are familiar with the  
3 invention and the facts and the issues in your case. And you certainly have  
4 20 minutes that you can spend however you like, but it would be most  
5 helpful to us if you focused on your particular issues in the case, and maybe  
6 we could start a bit with the claim interpretation. That would be helpful to  
7 us.

8 MR. FAZZARI: Is there a particular phrase?

9 JUDGE MILLS: I believe we'd like to look at the comprising  
10 language in the claim and whether it excludes the additional coating that we  
11 find in the other references.

12 MR. FAZZARI: Okay.

13 JUDGE LEBOVITZ: Yeah, if you could be more specific in claim  
14 34, one of the issues raised by the Examiner in steps B and C where it's  
15 drying the active layer formed during spraying to form a charged nucleus  
16 and then coating the charged nucleus.

17 MR. FAZZARI: Right. Right. Okay. Yes, this strikes me as claim  
18 construction. And the term we're talking about is "comprising," which is a  
19 transitional phrase. I'm sure you're familiar with I think are three basic  
20 categories. And in this instance, I guess I should back up. The term  
21 "comprising" is helpful to the Patent Office with respect to applications,  
22 because if claims were not open-ended, an applicant would have to describe  
23 every possible variation. And your applications would be longer and more  
24 difficult to examine than they are now. It helps the patentee because once  
25

1 he defines the kernel of his invention, if somebody else adds something  
2 later, the person is still covered.

3 The simple example, when I talk to people who are not familiar with  
4 patent law, I talk about a chair and I tell them, okay. You say it's a chair.  
5 Let me tell you what a patent attorney says. And I give him a very rough  
6 claim to a chair. And then I said, "And then remember when we were in  
7 school somebody put a little desk on the side of that chair." Now, it still has  
8 the elements A, B, C, but now we have element D. So it helps the patentee  
9 because it catches those who try to make improvements.

10 JUDGE LEBOVITZ: But in this case we have a charged nucleus and  
11 the Examiner says the charged nucleus can have the active layer on it and it  
12 could also have an intermediate layer. And I think your argument is that the  
13 charged nucleus can only have an active layer on it.

14 MR. FAZZARI: I think that's why I started out with the expression  
15 "claim construction." I think that any person with ordinary skill in the art or  
16 a court looking at this claim and reading the specification would see what he  
17 is talking about. It's very clear when you read the specification that the  
18 enteric coating is sprayed directly on the charged nucleus. In fact, if I had  
19 tried to amend these claims to say that there's a separating layer in between  
20 the charged nucleus and the sprayed enteric coating, the Examiner would  
21 have said new matter, new matter, new matter. Where do you find this in the  
22 specification?

23 JUDGE LEBOVITZ: Well, can you point to the specification where  
24 the skilled worker would find that the charged nucleus must be coated  
25 directly with the enteric coating?

1 MR. FAZZARI: Well, there are three examples in the specification in  
2 the application. And in each of the examples there's no indication that  
3 there's a separating layer or anything in between the charged nucleus and the  
4 sprayed-on enteric coating.

5 JUDGE LEBOVITZ: But to go back to your analogy, beginning the  
6 comprising language, you said it's to benefit the applicant and the inventor  
7 so as not requiring to describe every single step and to be able to claim the  
8 process generally. So when there are examples of this fact in this case you're  
9 asking us to read the example into the claim and read it more narrowly.  
10 You're saying in this case what we read by coating the charged nucleus,  
11 what we mean is coating the active layer. Because this says "coating the  
12 charged nucleus," not coating the active layer on the charged nucleus.

13 MR. FAZZARI: But the active layer is sprayed onto the charged  
14 nucleus. I'm sorry. The charged nucleus comprises like the sugar seed with  
15 the sprayed on layer that contains the active ingredient when it's sprayed on  
16 using the hydroalcoholic solution. I refer to the examples, because those  
17 were the quickest things, to be honest with you. I mean let me put it this  
18 way. That expression that you're referring to was never subjected to a 112  
19 rejection. The Examiner never questioned whether that was recited in the  
20 specification. The problem arises, the issue arises, is because the Examiner  
21 is construing the term "comprising" to contradict the expressed language of  
22 the claim, and that's the issue in this case with respect to comprising.

23 How can you use a transitional phrase to contradict what the clear  
24 language of the claim is, just by saying, well, comprising is open-ended.  
25 Well, that doesn't mean you can use it to contradict what is already stated in  
the claim and when that claim is consistent with the specification.

1 JUDGE MILLS: Could I ask another question about the claim, your  
2 last limitation in the claim regarding the Wurster type fluidized bed coater?  
3 Could you explain if that apparatus provides a different product than any  
4 other type of spray coating apparatus?

5 MR. FAZZARI: Well, I think it's the combination of steps in here,  
6 because the Wurster insert in a fluidized bed has been around since it was  
7 invented in 1959. The Examiner cites the wrong patent, by the way, but,  
8 you know, we're not going to argue that this Wurster insert in the fluidized  
9 bed was not known, because it certainly was known. In fact, the fellow I  
10 used to work with wrote an article about it that was sent in to the Examiner  
11 to show her what the Wurster bed was that was being referred to, but it  
12 basically was ignored. But it's the combination of steps. Does it give a  
13 different effect? I would imagine so.

14 There are three basic types of fluidized beds: the classical, the  
15 bubbling bed, and the circulating fluidized bed. This Wurster insert more or  
16 less allows you to operate more like a bubbling bed, or some people call it a  
17 spouting bed. So does it have some effect? I'm sure it does.

18 JUDGE LEBOVITZ: So you're not arguing here that it's the Wurster  
19 fluid bed that imparts the stability alone to the pharmaceutical?

20 MR. FAZZARI: The Wurster fluidized bed allows you to form the  
21 coating such that it has a substantially non-porous; and, in that respect, there  
22 probably is some impact to that.

1 JUDGE LEBOVITZ: Is there any evidence that the Wurster fluid bed  
2 imparts the non-porous coating, whereas, if you were to use other fluid bed  
3 apparatuses they would not impart a non-porous coating? Is there any  
4 evidence in the record of that?

5 MR. FAZZARI: Well, I don't think there's evidence about that. Well,  
6 let me say it the other way. There's certainly no evidence in the record that  
7 the use of other fluid beds gives you this result. There is the first Molina  
8 declaration, but that compares a different type of coater, because the  
9 Examiner kept on saying, "Well, a coater is a coater." You know, it's like  
10 aspirin. So in the first Molina declaration they did an experiment comparing  
11 the results using a coating apparatus from the Takeda patent. Takeda is the  
12 company that makes the Omeprazole product, Prevacid. I think that's what it  
13 is. And were shown, according to the Molina declaration, the resulting  
14 product from using this other type of coating apparatus did not have  
15 sufficient stability. It was not acceptable.

16 JUDGE LEBOVITZ: Right, and we saw that and discussed it, but the  
17 one issue that we were concerned about in that example that it wasn't  
18 comparative, so it's true that the declarant carried out the process in the WO,  
19 and then said you get deterioration or degradation.

20 MR. FAZZARI: Right.

21 JUDGE LEBOVITZ: But I believe they then said "But our product is  
22 stable," and the weakness of that for us was that it wasn't comparative. We  
23 don't know exactly whether all the conditions were the same, and the only  
24 thing different was the fluid bed apparatus. Because if there were other  
25

1 differences, we don't really know whether those other differences could  
2 account for the stability or the lack of stability.

3 MR. FAZZARI: Okay. That declaration was as I said because the  
4 Examiner was saying all excipients are alike. All coating apparatus, what's  
5 the difference. You're putting the coating on there. Who cares? What's the  
6 difference? So that's when you're talking about comparison I think of it in a  
7 little bit different way. This wasn't. I mean, of course, it was an  
8 obviousness issue, but it was the obviousness that had to do with the  
9 Examiner's thought about how all these coaters were interchangeable. And  
10 that's what that was addressing.

11 Now, with respect to this question about excipients, excipients are  
12 inactive ingredients. They have to be inactive. Otherwise, they would affect  
13 the active in a pharmaceutical dosage form.

14 JUDGE LEBOVITZ: But wouldn't it be obvious to try any fluid bed  
15 apparatus?

16 MR. FAZZARI: Well, what would be the motivation to try? If you  
17 start from the Examiner's position that all coating apparatuses are alike, what  
18 would be the motivation to change it?

19 JUDGE LEBOVITZ: Because of the equivalency?

20 MR. FAZZARI: You have no expectation of any different result. I  
21 mean if you're starting to go down the obvious to try approach, you know,  
22 obvious to try, I know, because of KSR and In re Kubin, obviousness to try -  
23 - I won't say has been resurrected -- but people are looking at it again. But  
24 still there's got to be some reasonable expectation of success. Here, the best  
25



1 that could be said is you'd have a reasonable expectation that it would do the  
2 same thing.

3 JUDGE GRIMES: Isn't that a reasonable expectation of success if  
4 you can obtain the same product by several known methods?

5 MR. FAZZARI: I'm sorry?

6 JUDGE GRIMES: Why wouldn't it be obvious to use any of those  
7 known numbers?

8 MR. FAZZARI: But then what is your expectation? Then we're  
9 going to go to the next step. We're going to go to the next step. Is it an  
10 unexpected result? So, even if you say yeah, it's obvious to try, and so it's  
11 prima facie obviousness, then we go to ah, but we have an unexpected result.

12 And if you've read through the record carefully, you'll see that one of the  
13 big problems that I've had or that we've had with this examination is that the  
14 Examiner would pigeonhole a showing for one specific purpose, and then  
15 ignore the other aspect. But mainly she seemed to be looking at questions of  
16 enablement and she didn't consider the showings with respect to questions of  
17 unexpected result or the expected improvement.

18 JUDGE LEOVITZ: Well, we did look at it carefully and we did see  
19 that you had raised that issue as once the Examiner sets up a prima facie  
20 case, it's incumbent upon the Examiner to listen to Appellant's rebuttal and  
21 then reconsider the whole case. The one thing that we had discussed was the  
22 Lovgren reference, as you pointed out, was before the D references. I can't  
23 remember how they're pronounced, but the D references. And that one does  
24 tell you that you don't need an intermediate coating between the PPI, the  
25 proton pump inhibitor, and the enteric coating. Right? So still Brooker was

1 aware of that, yet still the D references said it's optional. The intermediate  
2 coat is optional.

3 MR. FAZZARI: The D reference you mean Depui, D-e-p-u-i?

4 JUDGE LEBOVITZ: Depui, D-e-p-u-i. Sorry.

5 MR. FAZZARI: Okay. Right. Right. Well, I guess I can tell you. I  
6 can stand here and say I would like to be worth a billion dollars. Good goal.  
7 And then you turn to me and you say now how you going to do that? And I  
8 say, well, I just really don't know. And that's what Depui said, and there's a  
9 story about that reference in Astra. I was involved in the Omeprazole  
10 litigation, so I know a little bit about what was going on. But the argument  
11 is that he uses the word optional, doesn't give you the slightest idea of how  
12 to go about making this without a separating layer and getting a staple  
13 product. And the Lovgren reference which is cited, in the however you  
14 pronounce it patents, that reference specifically has data showing you what  
15 happens when you don't have the separating layer. So if I have some data  
16 that shows it doesn't work and someone comes along and says, well, it's  
17 optional, who is the one of ordinary skill in the art going to believe?

18 JUDGE LEBOVITZ: Would not In re Gurley indicate teaching away  
19 cases that say teaching away you can still have a suggestion to make an  
20 undesirable or inferior product. In other words, you can practice the prior art  
21 badly, but still practice it.

22 MR. FAZZARI: Well, that I would think that unexpected results still  
23 weighs towards patentability; and, that is the Lovgren reference is because  
24 I'm assuming you're going to ask me about KSR at some point today. The  
25 Lovgren reference, I think, is what does point away and what does

1     undermine the Examiner's position that because there's the word "optional,"  
2     that that means you can just take it out. You can't just take it out. It changes  
3     the whole formulation if you just take it out, especially when you're talking  
4     about in those two Astra references when you're starting to talk about mixing  
5     two active ingredients, because although excipients are supposed to be  
6     inactive, they're biologically inactive. One of the problems that started that  
7     led to the Lovgren and pill brand patents was the fact that things that were  
8     commonly used, i.e. enteric coatings, were causing a problem with respect to  
9     these substituted benzimidazoles, because they're so acid sensitive.

10       And the problem that they had was they wanted to protect the active  
11     ingredient from stomach acid, which is pH 1, which would have destroyed  
12     the stuff in about five minutes. It would have never gotten to the target cell,  
13     and so they put it on the enteric coating to protect it in the stomach. Then  
14     they found that even the acidity of the protective coatings was enough to  
15     start the degradation reaction of the active ingredient and that's what the art  
16     believed. And so then what they did after years of research, and I don't  
17     know how many formulations they tested -- I don't remember, I knew it at  
18     one time -- they came up with this intermediate separating layer, and that  
19     was the only way they could get a marketable product.

20       And the Federal Circuit just affirmed the last decision in the  
21     Omeprazole challenges. I'm not sure it's the last one, but the last one that I  
22     was aware of, and they discussed the validity of the Lovgren '505 and '230  
23     patents and they say that people in 1984 didn't even appreciate this problem,  
24     and they go on from there. And then they said, "But if they did appreciate  
25

1 the problem," and then they give two or three scenarios that one of ordinary  
2 skill in the art would follow, "none of them have to do with trying to do  
3 what was done by applicants here." What Applicant did here is contrary to  
4 what all the people who have marketable products are doing.

5 JUDGE LEBOVITZ: And we understand that, but it raises the issue.  
6 Well, what is it in the claim that's different? Because if you compare the  
7 Depui references, the '771 and the '184 patents, they look awfully similar.  
8 And the only difference is that the claim doesn't require the intermediate  
9 layer. Right? But, if you give credence to the optional and you say okay, it  
10 can be dropped. You might not get as good a product, but you can still get  
11 it, then your right up to the claim; and we can't really find, yet you're  
12 asserting that your product is much more stable, but we don't see what new  
13 claim makes it more stable. And how do you get this there?

14 MR. FAZZARI: I don't know if it's one particular step. I would say  
15 having the substantially non-porous nature of the layer, that is probably what  
16 it is, and that comes about going back to your earlier question, that comes  
17 about because of the Wurster fluidized bed, because of the spouting and  
18 circulatory phenomena you get. And one of the problems that I'm sure you  
19 saw this in the file, one of the problems we had was the lack of specificity of  
20 details of operation of any of the prior art examples, making it very difficult  
21 to make a side-by-side comparison. I don't think, offhand, I can't think of  
22 any examples of any of the references relied upon by the Examiner that had  
23 very much detail at all and so how do you know what you're comparing to?  
24 It's very difficult.

1 JUDGE MILLS: Have you established on the record in any location  
2 you could point us to where you have presented arguments that the process  
3 of Dupui would not result in a substantially not-porous layer?

4 MR. FAZZARI: I think it's the other way around. I think the  
5 burden was on the Examiner to come forth with something other than  
6 speculation. And I know the Patent Office doesn't have laboratories, but the  
7 speculation that there was that.

8 JUDGE MILLS: Was any argument or evidence presented in any  
9 declarations to that effect, or they weren't really focusing on it?

10 MR. FAZZARI: I think the closest one I would say is there was an  
11 argument in general that none of the prior art suggested that feature. There  
12 was a second declaration by a Johannsen or Johanneson that compared  
13 Example 5 of the Dupui references. I think it's the '771 patent and the  
14 conclusion there was also the resulting product that you got by just taking  
15 out the separating layer was not acceptable. There was rapid deterioration,  
16 and this was another point, because the Declarant said "This result doesn't  
17 surprise me." And, somehow, and I still don't understand it, the Examiner  
18 tried to turn it around and make it an admission against interest on the part of  
19 the applicant and I'm still baffled as to how that comes about.

20 JUDGE LEOVITZ: What was the admission, do you recall?

21 MR. FAZZARI: Well, the Declarant said this poor result based on the  
22 prior art doesn't surprise me, and she took the first sentence out of the  
23 paragraph. She didn't look to the rest of the paragraph, apparently, because  
24 it explained that because the prior art taught that if you didn't have a  
25

1 separating layer, you were going to have deterioration. And as I said, there  
2 were a number of examples in the Lovgren '505 patent.

3 And there was something that I just happened to notice last night that's  
4 not in the Appeal Brief, but it is in the '505 patent; and that's footnotes in  
5 column 14 under the table where it says when we're trying to do the example  
6 number 8, when they try to apply the enteric coating directly to the core, that  
7 while they were applying the emteric coating, it started to turn brown. And  
8 those skilled in the art, no matter what the Examiner says about all the  
9 excipients, those skilled in the art know that with these compounds, when  
10 they become discolored, it is the beginning of the degradation reaction. Part  
11 of the reason that the purple pill is in a purple gelatin capsule is so you can't  
12 tell if there are some pellets that were not perfect.

13 I think the main point that we want to make is that we do not think a  
14 prima facie was established. We think the Examiner ignored the Lovgren  
15 '505 patent, which is curious, because in paper number 16 -- I think it's  
16 August 16, 2002 -- she gave an obviousness rejection which included as one  
17 of the bases for the rejection the Lovgren patent. She may have cited the  
18 main European counterpart, but the disclosure was the same. So we believe  
19 that this taught away, and this has to be looked to in terms of the  
20 interpretation of the merit of optional. It could be optional, but if nobody  
21 knows how to do it, fine. What good does that do anybody?

22 We think that she violated In re Piasecki. She only was considering  
23 whether the arguments or submissions knock down her case and in fact,  
24 when the Lovgren examples were pointed out to her, she basically said well,  
25 I'm not relying on Lovgren in my rejection any more, so what's that got to

1 do with anything? I don't think that provision of 103 says considering the  
2 art as a whole allows the Examiner to take that position. Even if she had  
3 never cited Lovgren, if we submitted it that was evidence in the record and it  
4 should have been factored in. Going to the initial question of whether there  
5 was even a prima facie case.

6 And if she did establish a prima facie case, which we contest, we  
7 believe we made sufficient showings that there are unexpected results and  
8 benefits. The Examiner made I don't know how many requests for other  
9 showings, but it got to a point where she would speculate about something.  
10 We would counter the speculation, and then she would say well, do a test,  
11 and you can't do patent prosecution that way, I don't think, anyway.

12 JUDGE LEOVITZ: Yeah, I'm just looking. I just want to clarify in  
13 my mind one more thing. And we understand the Lovgren's argument that  
14 you're making.

15 MR. FAZZARI: And, by the way, there's a companion patent at '230  
16 Lovgren. The '505 is directed to Omeprazole. What Astra did is they filed a  
17 generic application dealing with acid labile substances and one specific to  
18 Omeprazole, because Omeprazole was going to be the product they  
19 marketed. But they wanted to like block other people out from similar  
20 things, but there's a list of a number of different types of acid labile  
21 compounds, because the Examiner did raise a question about well, you're  
22 only doing this sowing with respect to one or two substances. How do I  
23 know that the supply is generally. It's because all these compounds work the  
24 same way. They go through the same initial sequence when they start their  
25 degradation step.

1 JUDGE LEBOVITZ: Yeah, I'm just wondering if there's any  
2 disclosure. I mean when we asked you initially about the spraying active on  
3 the nucleus and then directly coating that with the enteric, I had asked you  
4 how would you understand that with the spec, and you pointed to the  
5 examples. So if there's anything you can recall from the spec by just turning  
6 the pages, if you wouldn't mind, because when we do claim interpretation as  
7 a skilled worker would understand it upon reading the spec.

8 MR. FAZZARI: Correct.

9 JUDGE LEBOVITZ: So that is a natural place to start. So in addition  
10 to the examples, if there's anything else you can point to, that would be  
11 helpful.

12 MR. FAZZARI: Well, if you look at the bottom of page 8 of the  
13 specification, it says "The new Galenical formulations, object of the present  
14 invention, are characterized in that there are spherical granules of the  
15 homogenous active charge layer and a very unporous surface formed by  
16 coating of an inert nucleus by spraying a single aqueous or hydroalcoholic  
17 mixture containing the active ingredient, antiulcer compound, together with  
18 the other excipients. Then in the same equipment and following a short  
19 drying period, the granules obtained are subject to a stage of enteric  
20 coating."

21 JUDGE LEBOVITZ: I think.

22 MR. FAZZARI: I'm sorry?

23 JUDGE LEBOVITZ: Thank you. I was just reading "unporous, the  
24 non-porous."  
25



1           MR. FAZZARI: I think you have the original photographs and you  
2 can see it sort of looks like the moon's surface a little bit. And it's hard to  
3 see in the copies, but let me just see. I think, oh, there's one thing doesn't  
4 show up in the record, but maybe you'd be interested in knowing this. I had  
5 heard at some point that there was another Astra patent. I don't know if it's  
6 prior art to this patent application or not, where under very specific  
7 conditions they were able to form an intermediate or separating layer in situ,  
8 but then it was a very narrow range of conditions. And as I say, I don't know  
9 if it's prior art. And maybe when the two primary references relied on by the  
10 Examiner use the term "optional," maybe they knew that that was in the  
11 works. I don't know if they've ever commercially used this or not; and I  
12 don't even know if it's true to be honest with you.

13           JUDGE MILLS: I don't believe we have any other questions for you.  
14 Thank you very much for your time.

15           MR. FAZZARI: Thank you.

16           (Whereupon, at 1:52 p.m., the proceedings were concluded.)  
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